IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Shunji Natsuka, et al.

Application No.: 10/700,505

Filed: November 5, 2003

FOR: MURINE ALPHA (1,3)
FUCOSYLTRANSFERASE FUC-TVII,
DNA ENCODING THE SAME,
METHOD FOR PREPARING THE
SAME, ANTIBODIES RECOGNIZING
THE SAME, IMMUNOASSAYS FOR
DETECTING THE SAME, PLASMIDS
CONTAINING SUCH DNA, AN CELLS
CONTAINING SUCH PLASMID

Customer No.: 20350

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Confirmation No. 9880

Examiner: Taevoon Kim

Technology Center/Art Unit; 1651

DECLARATION UNDER 37 C.F.R. § 1.131

- I, Kevin M. Gersten, together with my co-inventors, John B. Lowe and Shunji Natsuka, was at the time of the invention employed by the Regents of the University of Michigan, the assignee of the above-referenced patent application. At the time of the invention, I was a graduate student in the laboratory of Dr. John B. Lowe. I am, with my co-inventors, a named and true inventor of the subject matter disclosed and claimed in the above-referenced patent application.
- 2. The present invention provides a murine fucosyltransferase-VII ("Fuc-TVII") enzyme comprising a catalytic domain, wherein the enzyme has fucosyltransferase activity and is encoded by a murine nucleic acid sequence segment that is identical to a polynucleotide that is amplified using murine RNA or cDNA as a template by PCR using a 5' primer as shown in SEO ID NO:3 (GCGCGGATCCCACCATCCTTATCTGGCACTGGCCTTTCACC) and a 3'

primer as shown in SEQ ID NO:4 (GCGCGGATCCAGTTCAAGCCTGGAACCAGCTTTCAA GGTCTTC).

- 3. I, with my co-inventors, conceived of and reduced to practice the claimed invention in the United States prior to June 7, 1995, the filing date of U.S. Patent No. 5,858,752. The attached Exhibits A and B are pages from my notebook that provide evidence of the conception of the invention and its reduction to practice. Exhibit A, with dates redacted therefrom, includes order confirmations for primers corresponding to SEQ ID NO:3 and SEQ ID NO:4 prior to June 7, 1995. Exhibit B shows a laboratory notebook entry describing the successful cloning of murine Fuc-TVII stem region and catalytic domains from phage 104 using primer "624B" and "625B."
- 4. Page 1 of Exhibit A, with the dates blocked, shows primer "624B," which is a forward (sense) primer that is identical to SEQ ID NO:3. Page 2 of Exhibit A, with the dates blocked, shows primer "625B," which is a reverse (antisense) primer that corresponds to SEQ ID NO:4. Primer 625B is different from SEQ ID NO:4 at the three nucleotide bases in between the BamHI restriction endonuclease sequence (underlined) and the stop codon (in bold). Because the below primers are antisense, the stop codon read in the sense orientation is TGA (opal stop codon).

SEQ ID NO:4: GCGC<u>GGATCC</u>AGTTCAAGCCTGGAACCAGCTTTCAAGGTCTTC
625B: GCGCGGATCCTCATCAAGCCTGGAACCAGCTTTCAAGGTCTTC

- 5. SEQ ID NO:4 and primer 625B anneal to the identical coding sequence of murine Fuc-TVII. Primer pairs composed of SEQ ID NO:3 and SEQ ID NO:4 or 624B and 625B will amplify the same stem region and catalytic domain sequence from a murine Fuc-TVII nucleic acid template.
- 6. Exhibit B describes how primers 624B and 625B were used to amplify the stem and catalytic domains of murine Fuc-TVII. The stem and catalytic domain of murine Fuc-TVII were amplified from phage 104, which contains the murine Fuc-TVII gene. Exhibit B discusses specific PCR conditions and shows agarose gels of pET3b cloning plasmids with the cloned murine Fuc-TVII sequence excised by a BanHI restriction endonuclease treatment.

- 7. The above evidence demonstrates that prior to June 7, 1995 that I with my co-inventors had conceived of and reduced to practice the claimed invention. We had designed primers corresponding to SEQ ID NO:3 and SEQ ID NO:4 specifically for the amplification of murine Fuc-TVII stem region and catalytic domain from a murine Fuc-TVII gene template. We further used the primers to amplify and clone the murine Fuc-TVII stem region and catalytic domain.
- In view of the foregoing, I respectfully submit that the evidence provided in Exhibits A
 and B unequivocally establishes that the claimed invention was conceived of and reduced to
 practice prior to June 7, 1995.
- 9. I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that any such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

10. The Declarant has nothing further to say.

Dated: 3/16/07

Kevin M. Gersten

Attachments JLW:jlw